

§ 17.1

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§ 17.1 Scope.

This part sets forth practices and procedures for hearings concerning the administrative imposition of civil money penalties by FDA. Listed below are the statutory provisions that authorize civil money penalties that are governed by these procedures.

(a) Section 303(b)(2) and (b)(3) of the Federal Food, Drug, and Cosmetic Act (the act) authorizing civil money penalties for certain violations of the act that relate to prescription drug marketing practices.

(b) Section 303(f)(1) of the act authorizing civil money penalties for certain violations of the act that relate to medical devices and section 303(f)(2) of the act authorizing civil money penalties for certain violations of the act that relate to pesticide residues.

(c) Section 303(f)(3) of the act authorizing civil money penalties for certain violations relating to the submission of certifications and/or clinical trial information to the clinical trial data bank and section 303(f)(4) of the act authorizing civil money penalties for certain violations of the act relating to postmarket studies, clinical trial requirements, and risk evaluation and mitigation strategies for drugs.

(d) Section 303(g)(1) of the act authorizing civil money penalties for certain violations of the act that relate to dissemination of direct-to-consumer advertisements for approved drugs or biological products.

(e) Section 307 of the act authorizing civil money penalties for certain ac-

tions in connection with an abbreviated new drug application or certain actions in connection with a person or individual debarred under section 306 of the act.

(f) Section 539(b)(1) of the act authorizing civil money penalties for certain violations of the act that relate to electronic products.

(g) Section 351(d)(2) of the Public Health Service Act (the PHS Act) authorizing civil money penalties for violations of biologic recall orders.

(h) Section 354(h)(3) of the PHS Act, as amended by the Mammography Quality Standards Act of 1992 and the Mammography Quality Standards Act of 1998, authorizing civil money penalties for failure to obtain a certificate and failure to comply with established standards, among other things.

(i) Section 2128(b)(1) of the PHS Act authorizing civil money penalties for intentionally destroying, altering, falsifying, or concealing any record or report required to be prepared, maintained, or submitted by vaccine manufacturers under section 2128 of the PHS Act.

(j) Section 303(f) of the act authorizing civil money penalties for any person who violates a requirement of the Family Smoking Prevention and Tobacco Control Act which relates to tobacco products.

[60 FR 38626, July 27, 1995, as amended at 69 FR 43301, July 20, 2004; 73 FR 66752, Nov. 12, 2008; 75 FR 73953, Nov. 30, 2010]

§ 17.2 Maximum penalty amounts.

The following table shows maximum civil monetary penalties associated with the statutory provisions authorizing civil monetary penalties under the act or the Public Health Service Act.

CIVIL MONETARY PENALTIES AUTHORITIES ADMINISTERED BY FDA AND ADJUSTED MAXIMUM PENALTY AMOUNTS

U.S.C. Section	Former maximum penalty amount (in dollars) ¹	Assessment method	Date of last penalty figure or adjustment	Adjusted maximum penalty amount (in dollars)
21 U.S.C.				
333(b)(2)(A)	55,000	For each of the first two violations in any 10-year period.	2008	60,000.
333(b)(2)(B)	1,100,000	For each violation after the second conviction in any 10-year period.	2008	1,200,000.
333(b)(3)	110,000	Per violation	2008	120,000.
333(f)(1)(A)	16,500	Per violation	2008	16,500 (not adjusted).

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CIVIL MONETARY PENALTIES AUTHORITIES ADMINISTERED BY FDA AND ADJUSTED MAXIMUM PENALTY AMOUNTS—Continued

U.S.C. Section	Former maximum penalty amount (in dollars) ¹	Assessment method	Date of last penalty figure or adjustment	Adjusted maximum penalty amount (in dollars)
333(f)(1)(A)	1,100,000	For the aggregate of violations	2008	1,200,000.
333(f)(2)(A)	55,000	Per individual	2008	60,000.
333(f)(2)(A)	275,000	Per "any other person"	2008	300,000.
333(f)(2)(A)	550,000	For all violations adjudicated in a single proceeding.	2008	600,000.
333(f)(3)(A)	10,000	For all violations adjudicated in a single proceeding.	2007	10,000 (not adjusted).
333(f)(3)(B)	10,000	For each day the violation is not corrected after a 30-day period following notification until the violation is corrected.	2007	10,000 (not adjusted).
333(f)(4)(A)(i)	250,000	Per violation	2007	250,000 (not adjusted).
333(f)(4)(A)(i)	1,000,000	For all violations adjudicated in a single proceeding.	2007	1,000,000 (not adjusted).
333(f)(4)(A)(ii)	250,000	For the first 30-day period (or any portion thereof) of continued violation following notification.	2007	250,000 (not adjusted).
333(f)(4)(A)(ii)	1,000,000	For any 30-day period, where the amount doubles for every 30-day period of continued violation after the first 30-day period.	2007	1,000,000 (not adjusted).
333(f)(4)(A)(ii)	10,000,000	For all violations adjudicated in a single proceeding.	2007	10,000,000 (not adjusted).
333(f)(9)(A)	¹ N/A	Per violation	2009	15,000 (not adjusted).
333(f)(9)(A)	N/A	For all violations adjudicated in a single proceeding.	2009	1,000,000 (not adjusted).
333(f)(9)(B)(i)(I)	N/A	Per violation	2009	250,000 (not adjusted).
333(f)(9)(B)(i)(I)	N/A	For all violations adjudicated in a single proceeding.	2009	1,000,000 (not adjusted).
333(f)(9)(B)(i)(II)	N/A	For the first 30-day period (or any portion thereof) of continued violation following notification.	2009	250,000 (not adjusted).
333(f)(9)(B)(i)(II)	N/A	For any 30-day period, where the amount doubled for every 30-day period of continued violation after the first 30-day period.	2009	1,000,000 (not adjusted).
333(f)(9)(B)(i)(II)	N/A	For all violations adjudicated in a single proceeding.	2009	10,000,000 (not adjusted).
333(f)(9)(B)(ii)(I)	N/A	Per violation	2009	250,000 (not adjusted).
333(f)(9)(B)(ii)(I)	N/A	For all violations adjudicated in a single proceeding.	2009	1,000,000 (not adjusted).
333(f)(9)(B)(ii)(II)	N/A	For the first 30-day period (or any portion thereof) of continued violation following notification.	2009	250,000 (not adjusted).
333(f)(9)(B)(ii)(II)	N/A	For any 30-day period, where the amount doubled for every 30-day period of continued violation after the first 30-day period.	2009	1,000,000 (not adjusted).
333(f)(9)(B)(ii)(II)	N/A	For all violations adjudicated in a single proceeding.	2009	10,000,000 (not adjusted).
333(g)(1)	250,000	For the first violation in any 3-year period.	2007	250,000 (not adjusted).
333(g)(1)	500,000	For each subsequent violation in any 3-year period.	2007	500,000 (not adjusted).
333 note	N/A	For the second violation (following a first violation with warning) within a 12-month period by a retailer with an approved training program.	2009	250 (not adjusted).
333 note	N/A	For the third violation within a 24-month period by a retailer with an approved training program.	2009	500 (not adjusted).
333 note	N/A	For the fourth violation within a 24-month period by a retailer with an approved training program.	2009	2,000 (not adjusted).
333 note	N/A	For the fifth violation within a 36-month period by a retailer with an approved training program.	2009	5,000 (not adjusted).

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CIVIL MONETARY PENALTIES AUTHORITIES ADMINISTERED BY FDA AND ADJUSTED MAXIMUM PENALTY AMOUNTS—Continued

U.S.C. Section	Former maximum penalty amount (in dollars) ¹	Assessment method	Date of last penalty figure or adjustment	Adjusted maximum penalty amount (in dollars)
333 note	N/A	For the six or subsequent violation within a 48-month period by a retailer with an approved training program.	2009	10,000 (not adjusted).
333 note	N/A	For the first violation by a retailer without an approved training program.	2009	250 (not adjusted).
333 note	N/A	For the second violation within a 12-month period by a retailer without an approved training program.	2009	500 (not adjusted).
333 note	N/A	For the third violation within a 24-month period by a retailer without an approved training program.	2009	1,000 (not adjusted).
333 note	N/A	For the fourth violation within a 24-month period by a retailer without an approved training program.	2009	2,000 (not adjusted).
333 note	N/A	For the fifth violation within a 36-month period by a retailer without an approved training program.	2009	5,000 (not adjusted).
333 note	N/A	For the six or subsequent violation within a 48-month period by a retailer without an approved training program.	2009	10,000 (not adjusted).
335b(a)	275,000	Per violation for an individual	2008	300,000.
335b(a)	1,100,000	Per violation for “any other person”.	2008	1,200,000.
360pp(b)(1)	1,100	Per violation per person	2008	1,100 (not adjusted).
360pp(b)(1)	330,000	For any related series of violations	2008	355,000.
42 U.S.C.				
263b(h)(3)	11,000	Per violation	2008	11,000 (not adjusted).
300aa–28(b)(1) ..	110,000	Per occurrence	2008	120,000.

¹Maximum penalties assessed under The Family Smoking Prevention and Tobacco Control Act do not have a “former maximum penalty.”

[75 FR 73954, Nov. 30, 2010]

§ 17.3 Definitions.

The following definitions are applicable in this part:

(a) For specific acts giving rise to civil money penalty actions brought under 21 U.S.C. 333(g)(1):

(1) *Significant departure*, for the purpose of interpreting 21 U.S.C. 333(g)(1)(B)(i), means a departure from requirements that is either a single major incident or a series of incidents that collectively are consequential.

(2) *Knowing departure*, for the purposes of interpreting 21 U.S.C. 333(g)(1)(B)(i), means a departure from a requirement taken: (a) With actual knowledge that the action is such a departure, or (b) in deliberate ignorance

of a requirement, or (c) in reckless disregard of a requirement.

(3) *Minor violations*, for the purposes of interpreting 21 U.S.C. 333(g)(1)(B)(ii), means departures from requirements that do not rise to a level of a single major incident or a series of incidents that are collectively consequential.

(4) *Defective*, for the purposes of interpreting 21 U.S.C. 333(g)(1)(B)(iii), includes any defect in performance, manufacture, construction, components, materials, specifications, design, installation, maintenance, or service of a device, or any defect in mechanical, physical, or chemical properties of a device.

(b) *Person* or *respondent* includes an individual, partnership, corporation,